

**IN THE DRAWINGS:**

Please replace Figures 1, 3, 11, 12, 14, 19, 20 and 21 with the attached replacement sheets.

## **REMARKS**

In the Office Action dated October 8, 2008, claims 1, 8, 15-22, 28, 33, 38-47, 49, 50, 52-56, 60-63 and 66-74 are pending. The Examiner has made the restriction requirement final. Consequently, claims 43-47 and 69-71 are withdrawn from further consideration. Claims 1, 8, 15-22, 28, 33, 38-42, 49, 50, 52-56, 60-63, 66-68 and 72-74 are acted on in the Action. Claim 63 is allegedly an improper multiple dependent claim and therefore has not been examined on the merits. Claims 15, 39, 50 and 55-56 are objected to for certain informalities. The Examiner has also rejected various claims on the ground of indefiniteness under 35 U.S.C. §112, second paragraph. The specification and the drawings are objected to for a number of alleged informalities.

This Response addresses each of the Examiner's rejections and objections. Applicant therefore respectfully submits that the present application is in condition for allowance. Favorable consideration of all pending claims is therefore respectfully requested.

### ***Objections to Specification***

The specification is objected to for a number of alleged informalities.

Applicant has amended the specification to replace several spellings from the English style to the American style, and have corrected several typographical errors. The objections to the specification are obviated in light of the foregoing amendments. Withdrawal of the objections to the specification is respectfully requested.

### ***Objections to Drawings***

The drawings are also objected to for a number of alleged informalities.

Applicant has provided herewith replacement sheets for Figures 1, 3, 11, 12, 14, 19, 20 and 21.

With respect to the Examiner's objection to Figure 11, Applicant respectfully submits that when susceptible mice are infected with *P. berghei* ANKA malaria, they routinely die at day 6 of cerebral malaria. However, it is known to those skilled in the art, that if they survive the cerebral syndrome, they may also develop other pathologies such as metabolic acidosis or pulmonary oedema, which are sufficient to kill them. In the title of Figure 11, the term "cerebral malaria" has been taken to indicate the entire severe disease fatal syndrome, encompassing all fatal modalities, as this is standard usage among those skilled in the art. Figure 11 demonstrates survival, not one or more specific pathologies. Data presenting specific pathologies is given in Figures 15C-15E. To clarify, the title of Figure 11 is amended to read "fatal malaria."

In light of the replacement drawings and the foregoing remarks, it is respectfully submitted that the objections to the drawings are overcome. Withdrawal of the objections is respectfully requested.

#### ***Objections to Claims***

Claim 63 is allegedly an improper multiple dependent claim and therefore has not been examined on the merits. Applicant has canceled claim 63 from the claim listing, and has added new claims 75-79 to delineate the subject matter relating to a modular kit previously encompassed by claim 63.

Claims 15, 39, 50 and 55-56 are objected to for certain informalities. Applicant submits that the foregoing amendments to the claims address these informalities.

Accordingly, the objections to the claims are overcome and withdrawal thereof is respectfully requested.

**35 U.S.C. §112, Second Paragraph Rejections**

Claims 15-22 and 66-68 are rejected as allegedly indefinite because claim 15 recites the term "condition characterized by a parasite infection". The Examiner contends that the specification does not define the metes and bounds of the term "characterized".

Applicant has amended independent claim 15 to recite "a mammalian disease condition *caused* by a parasite infection". Support for this amendment is found throughout the specification, e.g., page 29, lines 16-26. The claims as amended are not indefinite.

Claims 20, 21, 41, 42, 49, 52-56, 60-62 and 72-74 are rejected as indefinite because certain base claims recite the phrase "derivative or equivalent thereof". According to the Examiner, while the specification provides examples of derivatives and equivalents of the structures recited in the claims, the specification does not actually define the metes and bounds of the terms.

Applicant has amended the claims to delete the references to "derivative or equivalent thereof" without prejudice, thereby obviating the rejection.

Claim 22, which depends from claims 1, 8 and 15, is allegedly indefinite, because of the limitation "wherein said disease condition is malaria". The Examiner states that this limitation lacks antecedent basis in claim 1.

In response, reference to claim 1 has been deleted from claim 22. Further, Applicant has also deleted the reference to claim 8 from claim 22, as claim 8 does not provide antecedent basis for the recited limitation either. However, new claims 80 and 81 have been added to properly depend from claims 1 and 8, and effectively delineate a disease condition being malaria. The rejection of claim 22 is obviated in light of the foregoing amendments.

Claims 28, 33, 38-42 and 66-68 are rejected for reciting the term "substantially". The Examiner contends that the specification does not define the metes and bounds of the term.

Applicant disagrees with the Examiner. Those skilled in the art would understand the metes and bounds of the term "substantially" in light of the instant disclosure. Further, Applicant submits that the term "substantially" is acknowledged by courts as permissible and warranted by the nature of the invention. See, e.g., *Verve, LLC v. Crane Cams, Inc.*, 311, F.3d 1116 (Fed. Cir. 2002); *Andrew Corp. V. Gabriel Elecs Inc.*, 847 F.2d 819, 821-22 (Fed. Cir. 1988). Therefore, Applicant respectfully submits that the claims reciting "substantially" are not indefinite.

Claims 1, 8, 15-22 and 66-68 are rejected as indefinite, because claims 1, 8 and 15 recite "an effective amount" of a composition which comprises the inositolglycan domain portion of GPI, and which inositolglycan domain portion comprises "insufficient lipidic domain to induce or elicit an immune response directed to said lipidic domain". The Examiner questions the relationship between "an effective amount" of the composition and the extent of the lipidic domain. Specifically, the Examiner has requested clarification as to whether the claims mean that, in the composition, the amount of lipidic domain is to be kept so low that under no amount of GPI is there to be an immune response to the lipidic domain, or, that under the minimum amount of GPI that elicits an immune response there is no response to the lipidic domain.

In response, Applicant submits that the phrases under objection mean that the amount of lipidic domain is sufficiently low that under the amount of GPI which is required to be administered to treat a mammal, an immune response to the lipidic domain is not elicited. Applicant respectfully submits that the claim language is clear to those skilled in the art in light of the disclosure in the specification.

Claims 50, 52-62 and 72-74 are rejected as indefinite because the expression "otherwise assessing" an immune response, recited in claim 50, is considered to be unclear. In addition, the reference to "said" complex formation in claim 50 allegedly lacks antecedent basis.

In response, the term "otherwise assessing" has been deleted from claim 50. The term "said" has also been deleted from the last part of the claim. The rejection is rendered moot in light of the amendments made to claim 50.

In view of the foregoing, it is respectfully submitted that the claims, as presently recited, are not indefinite. Withdrawal of the rejections under 35 U.S.C. §112, second paragraph, is respectfully requested.

***Conclusion***

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



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